REMARKS

Claims 1-13 are pending. Applicant respectfully requests reconsideration of this application in view of the following remarks.

In the Office Action dated February 25, 2009, claims 1-3, 5-10 and 13 were rejected under 35 U.S.C. § 102(b) as being anticipated by Bourgeois (US 6,126,611). Claims 1-3, 5-10 and 13 were rejected under 35 U.S.C. § 102(e) as being anticipated by Scheiner (US 6,1415,183). Claims 4, and 11-12 were rejected under 35 U.S.C. § 103(a) as being rendered obvious by Bourgeois or Scheiner. Applicant respectfully traverses the grounds for these rejections below.

I. 35 U.S.C. § 102(b) & (e) Rejections

"[A] claim is anticipated if each and every limitation is found either expressly or inherently in a single prior art reference." *Celeritas Techs., Ltd. v. Rockwell Int'l. Corp.*, 150 F.3d 1354, 1361, 47 U.S.P.Q.2d 1516, 1522 (Fed. Cir. 1998). The standard for lack of novelty, that is, for "anticipation," is one of strict identity. *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1296, 63 U.S.P.Q.2d 1597, 1600 (Fed. Cir. 2002).

A. Bourgeois Reference (US 6,126,611)

Although the Examiner is correct that Bourgeois discloses an apparatus for monitoring respiratory activity and heart rate, Bourgeois does not teach or suggest measuring hemodynamic state based on contractility of the myocardium. Heart rate does not correlate to myocardial contractility. The Examiner's statement that these are the same (Action, p. 2) is without support and incorrect. Contractility is a mechanical characteristic of the heart itself, whereas heart rate is merely the number of cycles of the hear per minute. Contractility represents the pressure at the

output of the heart and therefore is related to hemodynamics. Heart rate is, as noted, merely related to the rhythm of the heart. Claim 1 requires "means for measuring a hemodynamic state having an output hemodynamic signal representative of the contractility of the myocardium." The heart rate measurement in Bourgeois is not an output hemodynamic signal and is not "representative of the contractility of the myocardium." Therefore, because Bourgeois fails to disclose each and every element in claim 1, the Examiner's rejection should be withdrawn.

In addition, Bourgeois does not teach or suggest "conditionally modifying the treatment in relation to the contractility variation." In claim 1, once a sleep apnea is detected, the heart rate may or may not be increased, depending on the results of the measurement of the hemodynamic parameter (i.e., the contractility variation). Where the contractility variation is sufficiently decreased, a change in the heart rate or atrio-ventricular delay is effected. But where the contractility variation does not sufficiently decrease, no action on the heart is taken. In contrast, in Bourgeois, every single time a sleep apnea is detected, the device increases the heart rate to wake up the patient. The response of increasing the heart rate is not conditioned on any measurement of contractility variation. The invention in Bourgeois therefore lacks "means for conditionally modifying an operating parameter of the device to treat a detected apnea or hypopnea when said detected contractility variation is significant." For this additional reason, the Examiner's rejection of claim 1 should be withdrawn.

Claims 3, 5-10 and 13 depend from claim 1 and are allowable for at least the same reason that claim 1 is allowable. Accordingly, claims 3, 5-10 and 13 also should be allowed.

A. Scheiner Reference (US 6,415,183)

We respectfully traverse the Examiner's anticipation rejections based on Scheiner. In this regard, the Scheiner reference lacks the same limitation of "conditionally modifying the treatment in relation to the contractility variation" as discussed above in connection with Bourgeois. Although the Examiner is correct that Scheiner discloses a system that can measure intrathoracic impedance, Scheiner does not teach or suggest modifying the output response based on a measure of intrathoracic impedance. Claim 1 of the application makes clear that the treatment of the detected apnea is "conditionally modified" based on the "detected contractility variation." In this way, the apparatus of claim 1 does not stop the sleep apnea itself, but instead reduces the hemodynamic consequences of sleep apnea. Where there are no hemodynamic consequences of the sleep apnea, the apnea is allowed to continue without treatment until spontaneously resolved.

In contrast, the Scheiner reference refers to an apparatus that corrects the sleep apnea itself. In Scheiner, once sleep apnea is detected, an electronic output pulse is sent to the phrenic nerve to stimulate the diaphragm to cause respiratory activity. Additionally, Scheiner suggests that an output pulse may be sent to the heart to stimulate cardiac activity. Although the Examiner is correct that Scheiner discloses the ability to measure intrathoracic impedance, Scheiner does not teach or suggest using this measure to conditionally modify the output signal. Nowhere does Scheiner teach or suggest modifying the output pulse based on a contractility measure. For this reason, the Examiner's rejection of claim 1 should be withdrawn.

Claims 3, 5-10 and 13 depend from claim 1 and are allowable for at least the same reason that claim 1 is allowable. Accordingly, claims 3, 5-10 and 13 also should be allowed.

II. 35 U.S.C. § 103(a) Rejections

Dependent claims 4, and 11-12 were rejected under 35 U.S.C. § 103(a) as being rendered obvious by Bourgeois or Scheiner. We respectfully traverse.

To establish a *prima facie* case of obviousness, there must be: (1) some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine references teachings; (2) a reasonable expectation of success; and (3) prior art references which teach or suggest all of the claim limitations. *See In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000); MPEP § 2143 (8th Ed., Rev. 1). As discussed above, Bourgeois fails to disclose the means element found in independent claim 1 for "conditionally modifying an operating parameter of the device to treat a detected apnea or hypopnea when said detected contractility variation is significant." Neither does Scheiner disclose this element. Moreover, neither Bourgeois nor Scheiner would motivate one to modify the disclosed apparatus to include this functionality. Although Bourgeois discloses measuring heart rate, nothing in Bourgeois suggests measuring contractility or using a measure of contractility to modify the output signal. In fact, because the purpose of Bourgeois is to stop sleep apnea itself, and not to treat the hemodynamic effects of apnea, Bourgeois teaches away from any conditional modification of the output signal based on contractility. Bourgeois teaches to always output a cardiac stimulation upon a sufficient incident of apnea to wake the patient and remedy the apnea. The purpose of Scheiner is also to stop sleep apnea, and Scheiner similarly teaches away from such conditional modification. Scheiner teaches to always stimulate the phrenic nerve upon a sufficient incident of apnea to cause the diaphragm to resume

respiration. To modify the output signal in Bourgeois or Scheiner based on contractility would be contrary to the purpose of those inventions (to halt sleep apnea).

For the foregoing reasons, Applicant respectfully asks the Examiner to reconsider and withdraw the §103(a) rejections noted above.

CONCLUSION

Applicant respectfully submits that they have made a patentable contribution to the art. Reconsideration of this application in view of the foregoing remarks respectfully is requested.

The Examiner is invited to call Applicants' undersigned attorney if doing so would expedite prosecution.

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